DAKEWE

EU DECLARATION OF CONFORMITY

We, **Dakewe (Shenzhen) Medical Equipment Co., Ltd.** (SRN:CN-MF-000009696), located at Floor 5, Building B, No.2 Luhui Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen, China.

declare on our own responsibility, that the devices

Product	Basic UDI-DI
C10 Cassette Printer	69711825711VM
C100 Cassette Printer	
Omni Cassette Printer	
Cassette printer is intended to be used to print information on embedding cassette.	

comply with

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

IEC 61010-1:2010+A1:2016 IEC 61326-1:2020 EN ISO 13485:2016+A11:2021
IEC 61010-2-101:2018 IEC 61326-2-6:2020 ISO 14971:2019
IEC 60825-1:2014
Device classification: Class A

- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

EN IEC 63000:2018

The device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

European representative:

SUNGO Europe B.V. (SRN: NL-AR-000000247)
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den Ijssel, The Netherlands

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Signature: Teng Yu hao

Position: General manager

Date of issue: 2023. 8. 4

Place of issue: Floor 5, Building B, No.2 Luhui Road, Jinsha Community, Kengzi Street, Pingshan District, Shenzhen, China.

Digitally signed by Iurcu Nicolae
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